REMARKS

The Applicants acknowledge the Examiner's comprehensive Office Action with appreciation. Claims 1-7, 13-32, 39-41, 44, 45, and 48-55 remain pending in the application; however, Claims 23-25, 27-32, 45, and 48-55 remain withdrawn from consideration as a result of the previously issued Restriction Requirement. The Office maintains rejections under 35 USC § 102 and 35 USC § 103.

Claims 1-3, 6-7, 14-22, and 39-40 remain rejected as being anticipated under 35 USC § 102(b) by the disclosure of Parsons, et al. (WO 01/98253). The Office reiterates its position that Parsons, et al. disclose an example of a solution for injection which is preservative free (i.e., Example 4, which contains an active ingredient, sodium chloride and water) and that Parsons, et al. also disclose neramexane and the hydrochloride salt of neramexane as active ingredients. The Office also reiterates its position that one skilled in the art would "immediately envisage" the solution of Example 4 wherein neramexane and/or neramexane hydrochloride are used as the active ingredient.

The Office goes on to state that Parsons, et al. teach compositions "all for oral use", and that such compositions include solutions. It is the further position that Example 4 disclosed in the Parsons, et al. reference, although identified as a "solution for injection," would inherently be useful for oral administration. The Office states that this is evidenced by instant Claim 44, which depends from Claim 1, which is now directed to a formulation for oral administration containing water and neramexane mesylate and the fact that sodium chloride is commonly ingested with food. In view of this reasoning, the Office states that the disclosed solution, containing neramexane mesylate, purified water, and sodium chloride, would be suitable for oral administration. The Office cites In re Best (195 USPQ 430) and In re Fitzgerald (205 USPQ 594) to support its position with respect to inherency, stating that the burden is now shifted to the applicant to demonstrate that "the subject matter shown to be in the prior art does not possess the characteristic relied on."

The Applicants respectfully submit that, according to MPEP § 2112, in order to rely on a theory of inherency, the Office must provide "a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art." MPEP § 2112 also states that "the fact that a certain result or characteristic may occur or be present in the prior art is not enough to establish the inherency of that result or characteristic."

The Applicants further submit that, in the passage of Parsons, et al. relied on by the Office (i.e., page 21, last paragraph, to page 22, first paragraph), the reference discloses that the active ingredients of the invention may be formulated as liquids "...such as solutions, suspensions, emulsions, elixirs, or capsules ..., all for oral use; ... or in the form of sterile injectable solutions for parenteral (including intravenous or subcutaneous) use." Example 4 of the reference is a generic example relating to a solution for injection, and Examples 5-7 are generic examples relating to liquid oral formulations. The Office prejudicially overlooks the literal disclosure of Parsons, et al., which disclosure distinguishes between solutions for oral use, i.e., Examples 5-7, and solutions for injection, i.e., Example 4. If it was the intention of Parsons, et al. to inherently disclose "oral" solutions in Example 4, the "injection" descriptor would not have been included in Example 4. In view of the actual disclosure of the Parsons, et al. reference, the Applicants respectfully submit that one skilled in the art would not "immediately envisage" an oral dosage form comprising neramexane based on an example of a solution for injection (i.e., Example 4 of the Parsons, et al. reference).

Thus, the Applicants respectfully submit that the Office has not met this burden with respect to its allegation of inherency. Moreover, the Office citation of the applicants' claims to support its interpretation/extrapolation of what is disclosed in the cited reference amounts to improper hindsight reasoning. Therefore, the instant claims (directed to preservative free neramexane compositions for oral administration) are not anticipated by the Parsons, et al. disclosure.

Claims 1, 4-5, and 39-41 remain rejected for obviousness under 35 USC § 103(a) based on the disclosure of the above-mentioned Parsons, et al. reference. Claims

1, 13, 26, and 44 also remain rejected for obviousness under 35 USC § 103(a) based on the disclosure of Parsons, et al. in view of Gupta, et al. (US Published Application No. 2005/0014743). Although the Office acknowledges the Applicants' previously submitted argumentation with respect to the surprising and unexpected antimicrobial properties associated with the instant compositions, it is the position of the Office that the results demonstrated are not commensurate in scope with the rejected claims.

The Office states that the data disclosed in Tables 7-10 of the instant specification demonstrates antimicrobial activity of solutions of neramexane mesylate and purified water without any additional preservatives (or other additives) for neramexane mesylate concentrations of from 5-250 mg/mL. The Office goes on to state that Table 2, which discloses results for concentrations of neramexane at 0.5 mg/mL does not show the same antimicrobial activity since the results in Table 2 show growth of both Candida albicans and Apergillus niger.

The Offices further states that none of the rejected claims are limited to compositions comprising only two components (i.e., neramexane mesylate and water) for which surprising results are demonstrated and that there is no evidence that compositions comprising additional ingredients would possess antimicrobial activity. The Office also notes that there is no comparative data between the instantly claimed compositions and the composition of Example 4 of the Parsons, et al. reference and that the presence of sodium chloride would be expected to modify the neramexane mesylate concentrations that are effective for antimicrobial activity.

As noted above with respect to the anticipation rejection, the Applicants respectfully submit that the Office has not provided an adequate basis demonstrating the instant preservative free neramexane compositions for oral administration are inherent in the Parsons, et al. disclosure of a solution for injection. Thus, the instant compositions are not taught or suggested by the disclosure of the Parsons, et al. reference, alone or in combination with the Gupta, et al. disclosure. Moreover, one skilled in the art would recognize that the data disclosed in the specification may be extrapolated to provide support for compositions comprising further excipients and

the Office has provided no basis for its allegation that additional excipients would alter the antimicrobial properties of the instant preservative free neramexane compositions.

Reconsideration and withdrawal of the obviousness rejections under 35 USC § 103(a) is respectfully requested.

With respect to the previously issued Restriction Requirement, the Applicants respectfully reiterate that the instant invention, as amended, involves unity since the "special common technical feature" is a preservative free aqueous-based neramexane composition for oral administration. Moreover, in accordance with MPEP § 821.04, the Applicants respectfully request rejoinder of withdrawn Claims 23-25 and 27-32 upon the identification of allowable subject matter.

Finally, the Applicants note that the Office has not considered the reference (i.e., WO 99/55323) submitted in the Information Disclosure Statement (IDS) supplied with the Response and Amendment After Final of February 27, 2009. The Office indicates that no copy of the reference was provided. The Applicants note, however, that the Return Postal Card Receipt from the USPTO (enclosed herewith) indicates that the reference was received by the Office on March 2, 2009. Moreover, the reference is available in the Image File Wrapper (IFW) for the instant application on the USPTO website. The Applicants respectfully request that the Office consider the previously submitted reference and appropriately acknowledge such.

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Accordingly, consideration of the previously submitted reference, reconsideration of all grounds of objection and rejection, withdrawal thereof, and passage of this application to issue are all hereby respectfully solicited.

It should be apparent that the undersigned agent has made an earnest effort to place this application into condition for immediate allowance. If she can be of assistance to the Examiner in the elimination of any possibly-outstanding

insignificant impediment to an immediate allowance, the Examiner is respectfully invited to call her at her below-listed number for such purpose.

Allowance is solicited.

Respectfully submitted,

THE FIRM OF HUESCHEN AND SAGE

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Enclosure: Copy of Return Postal Card Receipt from Response and Amendment After Final of February 27, 2009 and Postal Card Receipt

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THE COMMISSIONER IS HEREBY AUTHORIZED TO CHARGE ANY FURTHER OR ADDITIONAL FEES WHICH MAY BE REQUIRED (DUE TO OMISSION, DEFICIENCY, OR OTHERWISE), OR TO CREDIT ANY OVERPAYMENT, TO DEPOSIT ACCOUNT NO. 08,3220.